

Message

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**From:** Wait, Monica [Wait.Monica@epa.gov]  
**Sent:** 1/6/2021 1:20:52 PM  
**To:** Peck, Charles [Peck.Charles@epa.gov]; Wagman, Michael [Wagman.Michael@epa.gov]  
**CC:** Shelby, Andrew [Shelby.Andrew@epa.gov]; Corbin, Mark [Corbin.Mark@epa.gov]; Jones, Kristin [jones.kristin@epa.gov]; Garber, Kristina [Garber.Kristina@epa.gov]  
**Subject:** RE: neonic PID-RTC - clothi comment

Hi everyone,

I made a few final editorial tweaks as I revised the response in the RTC document. Please see below and let me know if anything additional is needed. I'm also looping in Kris since this change was in response to her original comment, and the new response also references thiamethoxam. (Kris – read from the bottom up in the email thread if you want the full backstory.)

**4) Public comment regarding a response to the DER for MRID 50154301, submitted by Valent:**

**Summarized comments** – The registrant has recently submitted a frozen storage stability study in corn pollen (MRID 50711801) and surrogate nectar (MRID 50711802) to address concerns raised in the DER for MRID 50154301 that stability samples were not available to demonstrate stability of clothianidin and its analytes in corn pollen test samples from sampling through date of analysis (423 days post sampling). These studies indicate clothianidin and its analytes are stable in frozen storage samples.

**EFED Response:**

EPA thanks the registrant for submitting this data to address uncertainties discussed in the data evaluation record (DER) for MRID 50154301. EPA notes that parts of the 50154301 study were used quantitatively in the risk assessment for clothianidin, but that EPA determined that the trials with thiamethoxam-treated seeds could not be used quantitatively due to the lack of thiamethoxam analytical measurements. EPA will examine the submitted storage stability data (MRIDs 50711801 - 02) to see if it alters any of the scientific conclusions for the cited DER. While the storage stability data appear unlikely to change how the residue data were used in the risk assessment, it may increase the confidence in the clothianidin measured residue results.

Thanks,  
Monica

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**From:** Peck, Charles <Peck.Charles@epa.gov>  
**Sent:** Tuesday, January 5, 2021 3:35 PM  
**To:** Wagman, Michael <Wagman.Michael@epa.gov>  
**Cc:** Wait, Monica <Wait.Monica@epa.gov>; Shelby, Andrew <Shelby.Andrew@epa.gov>; Corbin, Mark <Corbin.Mark@epa.gov>; Jones, Kristin <jones.kristin@epa.gov>  
**Subject:** RE: neonic PID-RTC - clothi comment

Suggest the following revised version...

EPA thanks the registrant for submitting this data to address uncertainties noted in the DER. EPA notes that parts of the 50154301 study were used quantitatively in the risk assessment for clothianidin, but that EPA determined that the trials with thiamethoxam-treated seeds could not be used quantitatively due to the lack of thiamethoxam analytical measurements. EPA will examine the submitted storage stability data (MRID 50711801-02) to see if it alters any of the

scientific conclusions for the cited DER. While the study appears unlikely to change how this data was used in the risk assessment, it may increase the confidence in the clothianidin measured residue results.

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**From:** Wagman, Michael <Wagman.Michael@epa.gov>  
**Sent:** Tuesday, January 05, 2021 3:26 PM  
**To:** Peck, Charles <Peck.Charles@epa.gov>  
**Cc:** Wait, Monica <Wait.Monica@epa.gov>; Shelby, Andrew <Shelby.Andrew@epa.gov>; Corbin, Mark <Corbin.Mark@epa.gov>; Jones, Kristin <jones.kristin@epa.gov>  
**Subject:** RE: neonic PID-RTC - clothi comment

Thanks Chuck, that is helpful. So, how about this as a revised response:

EPA thanks the registrant for submitting this data to address uncertainties noted in the DER. EPA will examine the data to see if it alters any conclusions and/or study classification for the cited DER. EPA notes that parts of the 50154301 study were used quantitatively in the risk assessment for clothianidin, but that EPA determined that the trials with thiamethoxam-treated seeds could not be used quantitatively due to the lack of thiamethoxam analytical measurements. The submitted storage stability data (MRID 50711801-02) appear unlikely to change how this data was used in the risk assessment, but they may increase confidence in the clothianidin measured residue results.

Michael

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**From:** Peck, Charles <Peck.Charles@epa.gov>  
**Sent:** Tuesday, January 05, 2021 2:56 PM  
**To:** Wagman, Michael <Wagman.Michael@epa.gov>  
**Cc:** Wait, Monica <Wait.Monica@epa.gov>; Shelby, Andrew <Shelby.Andrew@epa.gov>; Corbin, Mark <Corbin.Mark@epa.gov>; Jones, Kristin <jones.kristin@epa.gov>  
**Subject:** RE: neonic PID-RTC - clothi comment

Looking at the DER, the study was classified as supplemental, but the data from the study could be used quantitatively in the risk assessment, except for data from trials 05-OH and 06-OH. Those trials used thiamethoxam-treated seeds and residues were only analyzed for clothianidin and its degradates and not thiamethoxam residues, so the data from those trials can only be considered qualitatively in the risk assessment. The following deficiencies were noted in the DER:

1. **Application methods and rates were not well documented in the study report. However, the reviewer was able to contact the registrant and receive confirmation of all seed treatment and soil treatment rates.**
2. Trials 05-OH and 06-OH used thiamethoxam-treated seed and residues were not analyzed for thiamethoxam. Therefore, the results of these two trials should be considered qualitative, at best. This is considered a major deviation for those two trials.
3. DT50 values could not be determined and trends could not be identified because pollen and soil samples were only collected at a single sampling interval in each trial. Additionally, carry over and year to year variability could not be assessed. Due to the nature of corn pollen development and sampling, these are considered minor deviations.
4. Only single composite soil samples were analyzed for each depth.
5. Concentrations were not measured in leaves.
6. **Trial 01-IA and Trial 04-IN were treated previously with clothianidin.**
7. Stability samples did not demonstrate stability of the analytes in the corn pollen test samples through to the date of analysis (423 days post-sampling).
8. Test sites had relatively clayey soils (as well as having high organic matter content [ $>1\%$ ]), which may have influenced (reduced) potential translocation of clothianidin residues from the soil to the corn plant. However, these soils are noted as being typical of this geographical region.

As we were able to use the study quantitatively for clothi and it doesn't address the issues for thia so it can be used quantitatively, I don't think it can be upgraded to acceptable for clothi, even with an acceptable stability study, as it doesn't help with estimating a DT50 value and only single composite soil samples were analyzed at each depth.

Michael – any thoughts?

Chuck

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**From:** Wagman, Michael <Wagman.Michael@epa.gov>  
**Sent:** Tuesday, January 05, 2021 2:33 PM  
**To:** Peck, Charles <Peck.Charles@epa.gov>  
**Subject:** RE: neonic PID-RTC - clothi comment

Thank you!

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**From:** Peck, Charles <Peck.Charles@epa.gov>  
**Sent:** Tuesday, January 05, 2021 2:15 PM  
**To:** Wagman, Michael <Wagman.Michael@epa.gov>; Wait, Monica <Wait.Monica@epa.gov>; Shelby, Andrew <Shelby.Andrew@epa.gov>  
**Cc:** Corbin, Mark <Corbin.Mark@epa.gov>; Jones, Kristin <jones.kristin@epa.gov>  
**Subject:** RE: neonic PID-RTC - clothi comment

I'll take a first cut at it...

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**From:** Wagman, Michael <Wagman.Michael@epa.gov>  
**Sent:** Tuesday, January 05, 2021 2:14 PM  
**To:** Peck, Charles <Peck.Charles@epa.gov>; Wait, Monica <Wait.Monica@epa.gov>; Shelby, Andrew <Shelby.Andrew@epa.gov>  
**Cc:** Corbin, Mark <Corbin.Mark@epa.gov>; Jones, Kristin <jones.kristin@epa.gov>  
**Subject:** RE: neonic PID-RTC - clothi comment

If you can do it, that would be great. I'm stuck in the middle of an aldicarb issue right now.

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**From:** Peck, Charles <Peck.Charles@epa.gov>  
**Sent:** Tuesday, January 05, 2021 2:13 PM  
**To:** Wait, Monica <Wait.Monica@epa.gov>; Wagman, Michael <Wagman.Michael@epa.gov>; Shelby, Andrew <Shelby.Andrew@epa.gov>  
**Cc:** Corbin, Mark <Corbin.Mark@epa.gov>; Jones, Kristin <jones.kristin@epa.gov>  
**Subject:** RE: neonic PID-RTC - clothi comment

So is this something Michael you will do, or would you like me to do this?

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**From:** Wait, Monica <Wait.Monica@epa.gov>  
**Sent:** Tuesday, January 05, 2021 2:02 PM  
**To:** Wagman, Michael <Wagman.Michael@epa.gov>; Peck, Charles <Peck.Charles@epa.gov>; Shelby, Andrew <Shelby.Andrew@epa.gov>  
**Cc:** Corbin, Mark <Corbin.Mark@epa.gov>; Jones, Kristin <jones.kristin@epa.gov>  
**Subject:** RE: neonic PID-RTC - clothi comment

Hello,

I think the main question is does the storage stability data change the interpretation or classification of the original DERs. Does the storage stability data cause the original study classifications to be upgraded or downgraded, or perhaps just change the listed deficiencies?

It would probably be helpful to go back to the original DERs referenced in the comment and see what those DERs say about missing storage stability and how that would be useful. And then figure out if the submitted storage stability information is good, bad, useful, not.

Cheers,  
Monica

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**From:** Wagman, Michael <Wagman.Michael@epa.gov>  
**Sent:** Tuesday, January 5, 2021 1:03 PM  
**To:** Peck, Charles <Peck.Charles@epa.gov>; Shelby, Andrew <Shelby.Andrew@epa.gov>; Wait, Monica <Wait.Monica@epa.gov>  
**Cc:** Corbin, Mark <Corbin.Mark@epa.gov>; Jones, Kristin <jones.kristin@epa.gov>  
**Subject:** RE: neonic PID-RTC - clothi comment

I don't think it requires a full review at this time—I think just noting if anything pops out as a significant issue at first glance. Right Monica?

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**From:** Peck, Charles <Peck.Charles@epa.gov>  
**Sent:** Tuesday, January 05, 2021 1:02 PM  
**To:** Shelby, Andrew <Shelby.Andrew@epa.gov>; Wait, Monica <Wait.Monica@epa.gov>; Wagman, Michael <Wagman.Michael@epa.gov>  
**Cc:** Corbin, Mark <Corbin.Mark@epa.gov>; Jones, Kristin <jones.kristin@epa.gov>  
**Subject:** RE: neonic PID-RTC - clothi comment

I have some time, so could probably review it. Will treat it like one of our typical soil or water storage stability studies...

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**From:** Shelby, Andrew <Shelby.Andrew@epa.gov>  
**Sent:** Tuesday, January 05, 2021 12:57 PM  
**To:** Wait, Monica <Wait.Monica@epa.gov>; Wagman, Michael <Wagman.Michael@epa.gov>; Peck, Charles <Peck.Charles@epa.gov>  
**Cc:** Corbin, Mark <Corbin.Mark@epa.gov>; Jones, Kristin <jones.kristin@epa.gov>  
**Subject:** RE: neonic PID-RTC - clothi comment

Monica,

Agreed that this study resides in a gray area between eco and fate. However, I've never reviewed a storage stability study for pollen or nectar so I'm not sure if I'm qualified to give it an authoritative skim. Additionally, bandwidth is pretty limited at my desk.

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**From:** Wait, Monica <Wait.Monica@epa.gov>  
**Sent:** Tuesday, January 5, 2021 12:46 PM  
**To:** Wagman, Michael <Wagman.Michael@epa.gov>; Peck, Charles <Peck.Charles@epa.gov>; Shelby, Andrew <Shelby.Andrew@epa.gov>  
**Cc:** Corbin, Mark <Corbin.Mark@epa.gov>; Jones, Kristin <jones.kristin@epa.gov>  
**Subject:** RE: neonic PID-RTC - clothi comment

Thanks Michael.

I'm looping in Andrew and Chuck on this email thread as well. Since it's a storage stability study, there is definitely a fate component. However, it's relevant to clothi residue studies which fell more in the eco wheelhouse last go round.

Please see the screen shot below for more details and MRID references. If anyone is able to chime in, or figure out a simple update to the EFED Response that is responsive to Kris' suggestion, let me know.

Thanks,  
Monica

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**From:** Wagman, Michael <Wagman.Michael@epa.gov>  
**Sent:** Tuesday, January 5, 2021 11:32 AM  
**To:** Wait, Monica <Wait.Monica@epa.gov>  
**Cc:** Corbin, Mark <Corbin.Mark@epa.gov>  
**Subject:** RE: neonic PID-RTC - clothi comment

I did, but forgot about it till now. My bandwidth is pretty limited right now, so I don't see being able to look at that study in any significant capacity in the near term. Given that it's a stability study, I wonder if a fate person might be able to look at it more efficiently then I would?


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**From:** Wait, Monica <Wait.Monica@epa.gov>  
**Sent:** Tuesday, January 05, 2021 11:26 AM  
**To:** Wagman, Michael <Wagman.Michael@epa.gov>  
**Cc:** Corbin, Mark <Corbin.Mark@epa.gov>  
**Subject:** neonic PID-RTC - clothi comment

Hi Michael,

Did you see the comment / question from Kris below which is in the clothi-specific section of the neonic RTC? Do you want to revise the EFED Response? I think we should make any changes as applicable to update the document and can then delete the comment bubble.

Thanks,  
Monica

<p>4) Public comment regarding a response to the DER for MRID 50154301, submitted by Valent:</p> <p>Summarized comments – The registrant has recently submitted a frozen storage stability study in corn pollen (MRID 50711801) and surrogate nectar (MRID 50711802) to address concerns raised in the DER for MRID 50154301 that stability samples were not available to demonstrate stability of clothianidin and its analytes in corn pollen test samples from sampling through date of analysis (423 days post sampling). These studies indicate clothianidin and its analytes are stable in frozen storage samples.</p> <p>EFED Response: EPA thanks the registrant for submitting this data to address uncertainties noted in the DER. EPA will examine the data to see if it alters any conclusions and/or study classification for the cited DER.</p> <p>5) Public comment regarding the chronic endpoint for freshwater aquatic invertebrates, submitted by Valent and BASF:</p> <p>Summarized comment – The registrants assert that the endpoint selected for risk assessment (NOAEC based on % emergence; Cavallaro, 2017) is from a study that differs dramatically in terms of its results</p>	<p> <b>Wagman, Michael</b> Sound reasonable Mark/Monica? Don't want to commit to reviewing it formally.</p> <p><b>Wait, Monica</b> Seems like a good approach to me.</p> <p><b>Garber, Kristina</b> Can we skim the submission to see if it generally meets our needs for upgrading the study?</p>
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